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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/518,076	03/03/00	SHAPIRO L	114232.109

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PEPPER HAMILTON
600 FOURTEENTH STREET NW
WASHINGTON DC 20005

HM12/0703

EXAMINER	
MOHAMED,A	
ART UNIT	PAPER NUMBER
1653	7

DATE MAILED: 07/03/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

Office Action Summary

Application No.	Applicant(s)
09/518,076	LELAND SHAPIRO
Examiner	**Art Unit**
ABDEL A. MOHAMED	1653

– The MAILING DATE of this communication appears on the cover sheet with the correspondence address –

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *30 days* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ ~~Responsive to communication(s) filed on~~ *for restriction purposes*

2a) ☐ This action is **FINAL.** 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-39* is/are pending in the applica

4a) Of the above, claim(s) _____ is/are withdrawn from considera

5) ☐ Claim(s) _____ is/are allowed.

6) ☐ Claim(s) _____ is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☒ Claims *1-39* are subject to restriction and/or election requirem

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☒ The drawing(s) filed on *Mar 3, 2000* is/are objected to by the Draftsman ~~Examiner~~.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)

16) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____

18) ☐ Interview Summary (PTO-413) Paper No(s). _____

19) ☐ Notice of Informal Patent Application (PTO-152)

20) ☐ Other:

RESTRICTION REQUIREMENT

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-15, drawn to a method of treating a subject suffering from a herpes virus infection or a disease arising from a herpes virus infection by administering a substance exhibiting mammalian alpha-1-antitrypsin (AAT) or AAT-like activity, classified in classes 514, 530 and 435, subclasses 2, 12, 16, 17, 867, 871, 934, 324, 329, 330, 350, 185,212, 213, 219, respectively.

II. Claim 16, drawn to a pharmaceutical composition for the treatment of herpes virus infection comprising a peptide of the general formula as recited in claim 16, classified in classes 514 and 530, subclasses 17, 329 and 330, respectively.

III. Claim 17, drawn to a method of treating a mammal suffering from a herpes virus infection that is mediated by endogenous host serine protease (SP) or SP-like activity by administering a substance exhibiting AAT or AAT-like activity, classified in classes 514, 530 and 435, subclasses 17, 329 and 212, respectively.

IV. Claim 18, drawn to a method of inhibiting in a mammal the spread or onset of a viral infection that is mediated by endogenous host serine protease (SP) or SP-like activity by administering a substance exhibiting AAT or AAT-like activity to a mammalian subject exposed or at risk of potential exposure to an agent of a viral infection that is mediated by endogenous host serine protease (SP) or SP-like

activity, classified in classes 514, 530 and 435, subclasses 12, 17, 934, 324, 329 and 319, respectively.

V. Claim 19, drawn to a method of treating a patient with a deficiency of functional endogenous AAT levels and suffering from a viral infection that is mediated by endogenous host serine protease (SP) or SP-like activity by administering to a patient a substance exhibiting AAT or AAT-like activity, classified in classes 514 and 435, subclasses 17 and 212 and 219, respectively .

VI. Claim 20, drawn to a method of treating an individual suffering from a viral infection that is mediated at least in part by serine protease activity by administering a substance exhibiting mammalian AAT or AAT-like activity, classified in classes 514 and 435, subclasses 12, 17 and 219, respectively.

VII. Claims 21-22, drawn to a method of preventing a deficiency of functional endogenous AAT levels in a mammalian patient susceptible to a viral infection that is mediated by endogenous host serine protease (SP) or SP-like activity by administering a substance exhibiting mammalian AAT or AAT-like activity, classified in classes 514, 530 and 435, subclasses 17, 934,329 and 313, respectively.

VIII. Claims 23-25, drawn to a pharmaceutical composition comprising a substance exhibiting mammalian AAT or AAT-like activity and a pharmaceutically acceptable carrier, classified in classes 514 and 435, subclasses 17 and 319, respectively.

IX. Claims 26-27, drawn to a method for the treatment of pre-existing lesions and sores of the skin or mucosa associated with a herpes virus and for prevention of future lesions and sores of the skin or mucosa thereof by administering a topical preparation comprising a substance exhibiting mammalian AAT or AAT-like activity, classified in classes 514 and 435, subclasses 17, 828 and 319, respectively.

X. Claims 28-30, drawn to a method for treating or preventing herpes by administering a substance exhibiting AAT or AAT-like activity, classified in classes 514, 530 and 435, subclasses 512, 517, 324, 329 and 185, respectively.

XI. Claims 31-32, drawn to a method of preventing sexually transmitted diseases by administering intravaginally or intrarectally a substance having AAT or AAT-like activity or a derivative thereof which inhibits caspase, proteinase-3, cathepsin G, elastase, or combination thereof, classified in classes 514 and 435, subclasses 17, 185, 212, 213 and 219, respectively.

XII. Claims 33-37, drawn to a method of treating a herpes virus infection topically by administering one or more compounds with AAT or AAT-like activity, classified in classes 514 and 435, subclasses 17, 828, 213 and 219, respectively.

XIII. Claims 38-39, drawn to a method of preventing or inhibiting entry of herpes viral nucleic acid into a mammalian host cell nucleus by administering a substance exhibiting mammalian AAT or AAT-like activity, classified in classes 514 and 345, subclasses 17, 934, 212, and 219, respectively.

2. The inventions are distinct, each from the other because:

Inventions II and I, III-VII, IX-XIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, methods I, III-VII and IX-XIII are alternative methods of use of the composition of Group II (claim 16) as claimed can be used in a materially different process such as in a pharmaceutical formulation to exhibit mammalian AAT or AAT-like activity as claimed in Group VIII (claim 23), and the methods of Groups I, III-VII and IX-XIII in addition to the composition of Group II have additional compounds and are used in various treatment/inhibition and/or prevention methods as disclosed in Groups I, III-VII and IX-XIII.

3. Inventions VIII and I, III-VII, IX-XIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, methods I, III-VII and IX-XIII are alternative methods of use of the composition of Group VII (claim 23) as claimed can be used in a materially different process such as in a pharmaceutical formulation for the treatment of a herpes virus infection which comprises a peptide of the general formula as recited in Group II (claim 16), and the methods of Groups I, III-VII and IX-XIII in addition to the composition of Group VIII have

additional compounds and are used in various treatment/inhibition and/or prevention methods as disclosed in Groups I, III-VII and IX-XIII.

4. Inventions I, III-VII and IX-XIII are related as independent methods which are not connected in design, operation or effect. The methods have different functions and different effects. The groups require different patent and literature search and a reference teaching treatment of herpes virus infection in a patient will not teach treatment of a herpes virus infection that is mediated by endogenous host serine protease (SP) or SP-like activity, nor inhibition of the spread or onset of a viral infection in general that is mediated by endogenous host SP or SP-like activity, or a deficiency of functional endogenous AAT levels or a viral infection in general which is mediated by SP activity, or prevention of a deficiency of functional endogenous AAT levels thereof, or preventing sexually transmitted diseases in general and *vice versa*. Therefore, the methods of Groups I, III-VII and IX-XIII for the intended treatment/inhibition and/or prevention as grouped are independent and distinct inventions which differ in material make up and composition requiring different reaction conditions. Hence, one does not require the other for ultimate use and as such is capable of separate manufacture, use and sale, and is novel and patentable over each other.

5. With respect to the pharmaceutical compositions of Groups II and VIII, the composition of Group II (claim 16) comprises a peptide of the general formula having chains of compounds comprising of various oligopeptide or poly amino acids that are different from each other while the composition of Group VIII (claim 23) comprises substances exhibiting AAT or AAT-like

activity in addition to a peptide or synthetic serpins. Thus, the pharmaceutical compositions (compounds) have different structures, functions and different effects. Therefore, the compositions of Groups II and VIII (although, they are used for the same methods, respectively) as grouped are independent and distinct inventions which differ in material make up and compositions requiring different reaction conditions. Hence, one doers not require the other for ultimate use and as such is capable of separate manufacture, use and sale, and is novel and unpatentable over each other.

6. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and because the searches for the individual groups are not coextensive, restriction for examination purposes as indicated is proper.

ELECTION OF SPECIES REQUIREMENT

7. If Applicant elects Group I, claim 1 is generic to a plurality of disclosed patentably distinct species comprising the following species:

Species I, diseases as recited in claim 3; Species II, viruses as recited in claim 8; Species III, the substance comprising a compound as recited in claim 9; Species IV, the substance comprising a peptide as recited in claim 10; and Species V, the substances as recited in claim 15.

If Applicant elects Group VII, claim 21 is generic to a plurality of disclosed patentably distinct species of the substances as recited in claim 22.

If Applicant elects Group X, claim 28 is generic to a plurality of disclosed patentably distinct species of the substance comprising a peptide as recited in claim 30.

Therefore, Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, (i.e., a single disease, or virus, or substance, or peptide) and to list all claims readable thereon including those subsequently added. Further, Applicant should include a chemical structure of the elected species/compound if it is not disclosed in the specification.

Should Applicant traverse on the ground that the species are not patentably distinct, Applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the Examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

8. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

CONCLUSION AND FUTURE CORRESPONDENCE

9. Claims 1-39 are subject to restriction or election requirement including species.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Abdel A. Mohamed whose telephone number is (703) 308-3966. The examiner can normally be reached on Monday through Friday from 7:30 a.m. to 5:00 p.m. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, can be reached on (703) 308-2923. The appropriate fax phone number for the organization where this application or proceeding is assigned is (703) 3084242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

CHRISTOPHER S. F. LOW
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

Mohamed/AAM

June 26, 2001